The opinion in support of the decision being entered today is not binding precedent of the Board.

Paper No. ~~119~~ 52

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

ALFRED POLLAK and ANNE GOODBODY,

Junior Party,
(Patent Nos. 5,662,885, 5,780,006
and 5,976,495),

v.

WILLIAM McBRIDE and RICHARD T. DEAN,

Senior Party
(Application 08/253,973).

Patent Interference 104,789 (MPT)

Before: LANE, TIERNEY and NAGUMO, Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

DECISION ON RULE 641 AND ORDER TO SHOW CAUSE

I. Summary of the Decision

This interference concerns metal radionuclide chelator compounds that bind metals at a

metal binding moiety and that also target specific tissues via a targeting moiety. Suitable metals include Technetium-99 (^{99}Tc), a radioactive tracer element. The compounds enable radio-imaging of specific tissues and are useful in diagnosis of various diseases and conditions. In particular, this interference relates to chelators having a monoamine-diamide-monothiol ("MADAT") structure.

A decision on preliminary motions was entered on October 31, 2003. (Memorandum, Opinion and Order, Paper No. 95). Concurrent with that decision, the Administrative Patent Judge charged with administering this interference entered: 1) a Rule 641 rejection against McBride's involved claims; and 2) an Order to Show Cause against Pollak's involved claims. (Rule 641 Rejection and Order to Show Cause, Paper No. 97). Specifically, in reviewing the evidence of record, the APJ determined that McBride's corresponding claims may be unpatentable over two Rodwell prior art references cited in Pollak Preliminary Motions 1 and 6. As the APJ's reasoning differed slightly from that put forth in Pollak's preliminary motions, the APJ rejected McBride's claims under Rule 641, which allowed McBride to file a response to the rejection of its claims. Additionally, as Pollak's claims appeared unpatentable over the Rodwell references cited in Pollak's preliminary motions, the APJ ordered Pollak to show cause why its claims were patentable over these references.

McBride opposes the Rule 641 rejection. (McBride Response to Rule 641 Rejection, Paper No. 101). In contrast, Pollak agrees with the Rule 641 rejection and has submitted arguments and evidence in support thereof. (Pollak Opposition to McBride Response to Rule 641 Rejection, Paper No. 115). Based upon the evidence of record, the panel concludes that

McBride's corresponding claims are unpatentable over the prior art Rodwell references.

Pollak opposed the Order to Show Cause against its claims only in the event that McBride's claims were found patenable over the Rodwell references. (Paper No. 104). As Pollak has failed to distinguish its claimed invention from that described by the Rodwell references, we hold that Pollak's claims are unpatentable over the Rodwell references.

McBride filed two preliminary motions with its Rule 641 response. The two motions do not alter our conclusion that McBride's claims are unpatentable and are denied.

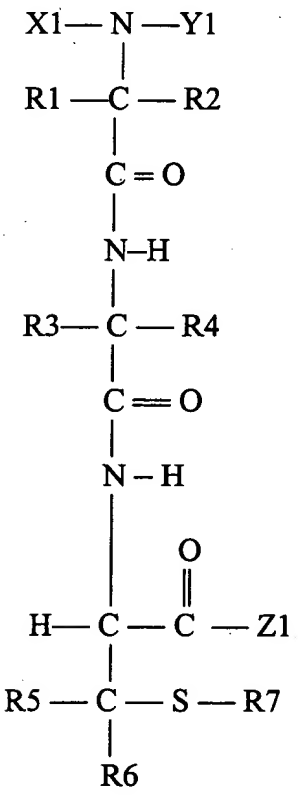
II. Findings of Fact

At the outset, we reaffirm the previous findings of fact and conclusions of law made in this interference to the extent they are consistent with this decision. Additional findings of fact are presented below.

1. The Count

1. Count 2 is the only count in interference and reads as follows:

A compound having the formula:



wherein

R1 is hydrogen (–H) or C_1–C_4 alkyl;

R2 is hydrogen (–H) or C_1–C_4 alkyl;

R3 is hydrogen (–H) or C_1–C_4 alkyl;

R4 is hydrogen (–H) or C_1–C_4 alkyl;

R5 is hydrogen (–H) or C_1–C_4 alkyl;

R6 is hydrogen (–H) or C_1–C_4 alkyl;

R7 is hydrogen (–H);

X1 is C_1–C_4 alkyl;

Y1 is C_1–C_4 alkyl;

Z1 is a targeting molecule; and

alkyl is a moiety having the empirical formula

$-C_nH_{2n+1}$, where n is 1 to 4,

or

the compound in a form complexed with a metal radionuclide,

or

a method of detecting the localization of a targeting molecule within a mammal comprising administering a diagnostically effective amount of the compound to a mammal wherein the compound is in a form complexed with a metal radionuclide,

or

a method of imaging a site of local inflammation within a mammal comprising administering a diagnostically effective amount of the compound to a mammal wherein the compound is in a form complexed with a metal radionuclide.

(Notice Redeclaring Interference, Paper No. 96).

2. McBride's Claimed Invention

2. McBride's involved '973 application was filed on June 3, 1994.

3. McBride claims 2, 3, 7 and 10 correspond to the count and are attached as Appendix A.

4. McBride claim 2 is an independent claim from which claims 3, 7 and 10 depend.

5. All of McBride's corresponding claims are directed to a reagent comprising: 1) a targeting moiety; 2) a metal chelator; and 3) a bivalent linking group that covalently links the targeting moiety to the metal chelator. (See, e.g., McBride claim 2).

6. McBride's targeting moiety can be a peptide. (See McBride U.S. Application No. 08/253,973 ("'973"), p. 22, lines 16-29, Paper No. 102, ¶ 3).

7. The chelator structure of McBride claims 2, 3 and 7 can be (amino acid)-(amino acid)-cysteine (X-X-C in the letter code for amino acids).

8. The chelator structure of McBride claim 10 includes Gly-Gly-Cys (GGC) and Arg-Gly-Cys (RGC).

9. McBride's metal chelator moiety peptide can be a tripeptide, such as YKC.[1]

10. McBride's bivalent linking group can be a peptide. (Paper No. 97, p. 17, Paper No. 102, ¶ 3).

11. McBride's claims 2, 3, 7 and 10 generally encompass a reagent comprising: 1) a tripeptide that is capable of chelating a metal; 2) a peptide targeting moiety; 3) where the peptide targeting moiety is covalently linked to the metal chelating tripeptide via a peptide bivalent linking group.

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[1]YKC represents the peptide: tyrosine-lysine-cysteine, also known as Tyr-Lys-Cys.

3. Pollak's Claimed Invention

12. Pollak is involved in the present interference based upon three patents. The patents and claims designated as corresponding in this interference are:

Pollak 5,662,885:	1-9 and 14-15
Pollak 5,780,006:	1-3, 5-6, 8-11 and 15-18
Pollak 5,976,495:	1-3, 5-6, 8-11 and 14-25

13. During the preliminary motions phase of this interference, Pollak did not contest the designation of the claims cited in fact ¶ 12.

14. Pollak Preliminary Motions 1 and 6 allege that McBride's corresponding claims are unpatentable over the teachings of the Rodwell references. (Pollak Preliminary Motion 1; Paper No. 48, Pollak Preliminary Motion 6, Paper No. 39).

15. Pollak Preliminary Motions 1 and 6 failed to explain why Pollak's claims were patentable over the prior art Rodwell references.

4. Rodwell WO 91/17173 and U.S. Patent No. 5,196,510

16. Rodwell WO 91/17173 ("Rodwell '173 ") published on November 14, 1991. (PX 2004, front page).

17. Rodwell U.S. Patent No. 5,196,510 ("Rodwell '510 ") issued on March 23, 1993. (PX 2005, front page).[2]

18. Both Rodwell '173 and '510 are available as prior art against McBride '973 under 35 U.S.C. §102(b).

19. For purposes of review, both McBride and Pollak agree that Rodwell '173 and '510 contain substantially identical disclosures. (Paper No. 48, p. 5, ¶24, Paper No. 60, p. 5 and Paper No. 64, p. 5).

20. Rodwell '173 claims a conjugate of a molecular recognition unit (targeting moiety) linked to an effector domain (metal chelator) where the effector domain may be YKCGLCERSFVEKSALSRHQRVKKN ("YKC metal binding peptide"). (PX 2004, p. 60, claim 8).

21. Rodwell '173 exemplified molecular recognition unit (targeting moiety) conjugates that exhibited "localization" and permitted imaging of the desired target regardless of whether or not the effector domain (metal chelator) was on either the amino terminus or on the carboxy terminus of the binding domain. (PX 2004, p. 57, lines 9-17).

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[2]Pollak's exhibits are designated PX whereas McBride's exhibits are referred to as MX.

22. The carboxy terminus of Rodwell's YKC metal binding peptide is a string of amino acids, i.e., a peptide. For example, the carboxy terminus of Rodwell's YKC metal binding peptide (GLCERSFVEKSALSRHQRVKKN) links the YKC metal binding peptide to Rodwell's targeting moiety. (PX 2004, p. 60, claim 8).

5. Third Declaration of Dr. Lister-James on Behalf of McBride

23. Dr. Lister-James testifies that he agrees with the findings of fact set forth in the Rule 641 rejection, except for a portion of paragraph 21. (MX 1025, ¶6).

24. Dr. Lister-James testifies that paragraph 21 of the Rule 641 rejection improperly infers that the YKC portion of the amino acid sequence YKCGLCERSFVEKSALSRHQRVKKN functions as a metal binding peptide. (MX 1025, ¶¶ 6-7).

25. Dr. Lister-James is of the opinion that the presence of two thiol groups (of the two cysteine residues) in Rodwell's peptide renders moot the stability to be gained by formation of the 5:5:5 chelate complex. (MX 1025, ¶ 9).

26. Dr. Lister-James testifies that he directed that a High Performance Liquid Chromatography (HPLC) experiment be performed to determine whether Rodwell's YKC peptide forms a Tc-99m complex with the N-terminal YKC-sequence. (MX 1025, ¶¶ 11, 14).

27. Dr. Lister-James's experiments involved four peptides: 1) the Rodwell YKC peptide; 2) the N-terminal 9-mer derived from Rodwell; 3) the N-terminal 9-mer derived from Rodwell with the second cysteine thiol blocked by methylation; 4) the N-terminal 9-mer derived from Rodwell with the first cysteine thiol blocked by methylation. (MX 1025, ¶ 13).

28. The results of Dr. Lister-James's experiments are attached at Tab C of his declaration and the results are summarized in Table 2. (MX 1025, ¶ 15).

29. According to Dr. Lister-James, monoamine, diamide thiol (MADAT) and triamide thiol (TAT) chelators "are known to give syn and anti isomeric technetium complexes which may be seen as separate components upon analysis by HPLC." (MX 1025, ¶ 15). Due to the apparent syn and anti HPLC peaks, Table 2 reports the radiochemical purity (RCP) "as the sum of the % of the two largest peaks in the HPLC chromatogram." (MX 1025, ¶ 15). Dr. Lister-James testifies that the calculated RCP "therefore represents the 'best case' (highest possible) result." (MX 1025, ¶ 15).

30. Dr. Lister-James found a 64.8% initial RCP for 100 micrograms of Rodwell YKC peptide. In contrast, again for 100 micrograms, Dr. Lister-James reports a 59.4% initial RCP for the 9-mer sequence derived from Rodwell and 100% initial RCP for the methylated 9-mer sequences derived from Rodwell. (MX 1025, Table 2).

31. Dr. Lister-James concludes that the results of his experiments demonstrate that the Rodwell YKC peptide and its N-terminal 9-mer gave a mixture of Tc-99m products. (MX 1025, ¶ 16).

32. Dr. Lister-James further concludes that:

> Even if one of the mixture of technetium complexes was a MADAT complex, it was formed in such low radiolabeling yields (RCP ≤ 65%) that it must be considered not to be commercially useful.

(MX 1025, ¶ 16).

6. February 6, 2004 Deposition of Dr. Lister-James

33. Dr. Lister-James testified that it was reasonable to infer from his experiments that YKC, when it is by itself, will complex technetium. (PX 2052, p. 46, line 9 to p. 47, line 22).

34. McBride's involved '973 specification concludes, without conducting any analytic measurements, such as NMR or x-ray crystallography, that peptides listed therein will form a 5:5:5 monoamine diamide monothiol structure because "[i]t was known to be a stable configuration of other types of technetium complexes." (PX 2052, p. 54, line 18 to p. 57, line 13).

35. Dr. Lister-James testified that he could have but did not use NMR equipment to discern whether or not the Rodwell YKC peptide produced YKC coordination with technetium. (PX 2052, p. 48, line 22 to p. 50, line 13).

36. Dr. Lister-James testified that the purity levels of the YKC peptides reported in his declaration experiment were inadvertently reported as being higher than they actually were, i.e., 97% vs. 76%. (PX 2052, p. 97, line 22 to p. 105, line 8).

7. Fourth Declaration of Dr. Karen Linder on Behalf of Pollak

37. Dr. Linder testifies as to the expected ring structure for the Rodwell YKC metal binding peptide and reiterates her belief that:

> Therefore, contrary to Dr. Lister James' conclusion at ¶ 10 of the Third Lister-James Declaration, this 5:5:5 YKC monoamine bisamide monothiol ring structure is a structure which one of ordinary skill in the art would have expected to form upon coordination with technetium.

(PX 2046, ¶ 17).

38. In reviewing Dr. Lister-James' HPLC experiments with the YKC metal binding peptide, Dr. Linder testifies that:

1) However, it is well established in the art that HPLC alone cannot be used to determine the location of the Tc-99m coordination to the Rodwell compound. (PX 2046, ¶ 24).

2) However, without any further analysis, an HPLC chromatogram, in and of itself, does not yield any specific information that could be used to determine which

sequence in the Rodwell compound the Tc-99m ion has coordinated with. (PX 2046, ¶ 25).

3) Further experiments, such as x-ray crystallography, UV-Vis spectroscopy, mass spectrometry, NMR, and/or elemental analysis, etc. must be performed to determine the exact sequence in a peptide to which a metal ion such as technetium has coordinated with. (PX 2046, ¶ 26).

4) Furthermore, Dr. Lister-James' experiments are seriously flawed because they were performed with the Rodwell compound having only 76% purity as determined by HPLC. Such high amounts of impurities present in the sample could, if the impurities can also chelate to Tc, adversely affect the radiolabeling results of the Rodwell compound with Tc-99m. In other words, such high amounts of impurities will consequently result in either a lower and/or inaccurate radiochemical purity ("RCP") test result. (PX 2046, ¶ 28, internal citations omitted).

39. Regarding Dr. Lister-James' comments regarding the commercial utility of Rodwell's YKC metal binding peptide, Dr. Linder testifies that:

1) Moreover, Dr. Lister-James' reliance on my testimony is also incorrect – I did not, as he so alleges, testify that a RCP of 90% was necessary for "commercial utility." Rather, I identified the 90% RCP as the target for *in vivo* administration in humans, not as the standard for "commercial utility." (PX 2046, ¶ 30).

2) Since Dr. Lister-James otherwise made no attempt to optimize or refine his experiments so as to obtain this 90% target radiochemical purity, Dr. Lister-James thus has no scientifically sound basis for concluding from his two experiments that the Rodwell compound would not radiolabel in a "commercially useful" yield. (PX 2046, ¶ 32).

40. Dr. Linder testifies that she designed an experiment to confirm which sequence in the YKC metal binding peptide chelates Tc-99m. (PX 2046, ¶¶ 33-34).

41. Dr. Linder provides a detailed accounting of the process by which the Pollak HPLC and NMR experiments were designed and conducted. (PX 2046, ¶¶ 37-93).

42. Dr. Linder testifies as to the results of Pollak's HPLC and NMR experiments as follows:

1) For any given sample in which the Rodwell compound was complexed with Tc-99m, there was always a measurable amount of Tc-99m coordination at the YKC sequence of the Rodwell compound (as determined by comparison to an authentic standard of this compound). (PX 2046, ¶ 35).

2) The formation of a 5:5:5 ring structure (and thus Tc-99m coordination at the YKC sequence) was the overwhelming favored form of the Tc-99m complexed Rodwell compound, thus confirming that the 5:5:5 formation with the YKC sequence is also the most stable and preferred structure, as consistent with the established precepts of technetium chemistry. (PX 2046, ¶ 35).

3) The RCP of the major product peak (i.e., Peak 4) of the Tc-99m complexes of the Rodwell compound prepared using procedures developed in our laboratory was significantly higher than that of corresponding compound prepared under the conditions reported by Dr. Lister-James. Specifically, as reported in ¶ 87 *supra*, the actual initial RCP of the complexes containing Tc-99m coordination at the YKC sequence was over 85%. (PX 2046, ¶ 96).

4) Therefore, these experiments establish conclusively that Tc-99m in the chelated complexes of the Rodwell compound prepared by Dr. Lister-James predominantly coordinate to the YKC sequence of the Rodwell compound. (PX 2046, ¶ 95).

8. Binding of the YKC Peptide

43. We credit Dr. Linder's testimony and supporting HPLC and NMR evidence that in her experiments there was always a measurable amount of Tc-99m coordination at the YKC sequence of the Rodwell YKC metal binding peptide.

44. We credit Dr. Linder's testimony and supporting HPLC and NMR evidence that Tc-99m predominantly coordinates to the YKC sequence of Rodwell's YKC metal binding peptide.

45. We find that Dr. Lister-James' testimony and HPLC evidence are not inconsistent with Dr. Linder's testimony that Tc-99m predominantly coordinates to the YKC sequence of Rodwell's YKC metal binding peptide. (See, e.g., MX 1025, ¶ 16 where Dr. Lister-James' testifies that McBride's experiments indicated that the RCP for the Rodwell YKC metal binding peptide at the YKC sequence could be up to 65%).

46. We credit Dr. Linder's testimony and HPLC and NMR evidence as demonstrating the formation of a 5:5:5 ring structure was the favored form of the Tc-99m complexed Rodwell YKC metal binding peptide.

III. Opinion

A. Rule 641 Rejection of McBride's Corresponding Claims

McBride's corresponding claims, 2, 3, and 7 stand rejected under 35 U.S.C. §102(b) as anticipated by Rodwell '173 and by Rodwell '510. McBride's corresponding claim 10 stands rejected under 35 U.S.C. §103 as obvious over Rodwell '173 and/or '510. (Paper No 97). Additionally, Pollak was Ordered to Show Cause why the Rule 641 rejection of McBride's corresponding claims over the Rodwell references does not also render Pollak's corresponding claims unpatentable. (Paper No. 97, p. 26 and see above finding of fact ¶ 12).

McBride opposes the Rule 641 rejection of its claims. (Paper No. 101). In contrast, Pollak agrees that the parties' claims are unpatentable over the Rodwell references; but Pollak argues that if it should be determined that McBride's claims are patentable over these references, then its claims are likewise patentable. (Paper Nos. 104 and 115).

McBride has presented several arguments as to why McBride's corresponding claims are patentable over the teachings of the Rodwell references. Generally, McBride argues that Dr. Lister-James' experiments demonstrate that, while it is possible that some MADAT complex is formed, the MADAT formation is not an invariable result and that the level of MADAT formation is below the required commercial purity levels. (Paper No. 101, ¶ 9). McBride also argues that one skilled in the art would understand Cox, WO 92/21383 as teaching that Tc-99m will bind to both cysteine amino acid radicals in the Rodwell YKC metal binding peptide as opposed to the 5:5:5 formation where the metal cation complexes with the YKC portion of the peptide. (Paper No. 101, ¶ 9). These arguments are addressed below.

1. Inherent Complexing of Tc-99m with the YKC Portion of Rodwell's YKC Metal Binding Peptides

McBride argues that Dr. Lister-James' testimony demonstrates that the formation of a MADAT complex is not an invariable result of labelling the Rodwell YKC metal binding peptide. According to McBride, the Tc-99m radiolabelling of Rodwell's YKC metal binding peptide leads to mixtures with low RCP values (RCP ≤ 65%) and that this low level of binding is well below the 90% purity level that is required to be commercially useful. (Paper No. 101, ¶ 9 and MX 1025, ¶ 16). Specifically, McBride alleges:

> Lister-James Declaration No. 3 shows clearly that the tripeptide YKC is not inherently disclosed by Rodwell as the chelating moiety in the 25-mer amino acid sequence beginning with this tripeptide. As explained by Dr. Lister-James in paragraph 16, it is possible that some MADAT complex is formed from the labelling reaction, but it is not the invariable result of said reaction and, to the extent that a MADAT complex may be produced, it is well below the 90% purity level required according to paragraph 38 of Linder Declaration II (PX 2029).

(Paper No. 101, ¶ 9).

Dr. Lister-James' cited testimony is reproduced below:

> 16. The Tc-99m radiolabeling results clearly show that the Rodwell peptide sequence and its N-terminal 9-mer, each containing two free thiol groups, (Peptides 1 and 2) give a mixture of Tc-99m products. Even if one of the mixture of technetium complexes was a MADAT complex, it was formed in such a low radiolabeling yields [sic] (RCP ≤ 65%) that it must be considered not to be commercially useful (Dr. Linder made the point in Linder II, para. 38, that a 90% radiochemical yield is needed for commercial utility.) In contrast, the two peptides with only one thiol-containing chelating sequence (Peptides 3 and 4) each gave only a single radiolabeled product (*i.e.*, a single pair of HPLC peaks expected to be the syn/anti isomers of the technetium complex), and had exceptionally high radiolabeling yields (≥ 97%). Thus, peptides with a single thiol-containing moiety can be labeled with Tc-99m cleanly and selectively but, if more than one thiol-containing amino acid sequence is present in the molecule, a mixture of products and low yields are observed.

(MX 1025, ¶ 16).

a. McBride's Claims not Limited to Commercially Useful RCP Values

McBride appears to be of the opinion that its claims are limited to commercially useful amounts of its claimed reagants. We disagree.

In interpreting McBride's claims, we give the language of the claims their broadest reasonable interpretation as they would be understood by one of ordinary skill in the art. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). To understand the meaning of a claim, we look first to the intrinsic evidence of record, *i.e.*, the application itself, including the claims, and the specification. Within this intrinsic evidence, the appropriate starting point is always the language of the claims. A claim term should be given its ordinary meaning as it is understood in

the art unless the specification provides a special, different meaning or definition. *ACTV, Inc. v. The Walt Disney Co.* 346 F3d 1082, 1088, 68 USPQ2d 1516, 1521 (Fed. Cir. 2003); *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366, 62 USPQ2d 1658, 1662-63 (Fed. Cir. 2002).

McBride's claims do not explicitly recite a particular RCP value for its claimed reagants. Further, McBride has failed to explain how its specification limits its claims to specific RCP values or excludes the presence of additional non MADAT reagants. Lacking any such guidance from the claims themselves or an express definition in McBride's specification, we reject McBride's invitation to read a "commercially useful" RCP limitation into McBride's claims.

Additionally, we note that the 90% purity level referred to by McBride as "commercially useful" is the RCP target for *in vivo* administration in humans. (PX 2046, ¶ 30). There are no limitations as to radiochemical purity in McBride's claims to the reagants. Also, one skilled in the art recognizes that the optimization of RCP values is customary in the radiopharmaceutical art. (PX 2046, ¶ 31).

b. Complexing of Tc-99m with the YKC Portion of Rodwell's YKC Metal Binding Peptides is an Inevitable Result

Inherency is not established by probabilities or possibilities. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999). The mere fact that a certain thing may result from a given set of circumstances is not sufficient to demonstrate inherency. *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). Additionally, the Federal Circuit has stated that:

> Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter. The extent of the inherent disclosure does not limit its anticipatory effect. In general, a limitation or the entire invention is inherent and in the public domain if it is the "natural result flowing from" the explicit disclosure of the prior art.

Schering Corp. v. Geneva Pharmaceuticals Inc., 339 F.3d 1373, 1379, 67 USPQ2d 1664, 1669 (Fed. Cir. 2003).

McBride argues that the formation of Tc-99m complex at the YKC portion of Rodwell's compound is not an "invariable" result. (Paper No. 101, ¶ 9). For this proposition, McBride relies upon the testimony of Dr. Lister-James. Yet, McBride fails to direct our attention to where Dr. Lister-James' testifies that the formation of Tc-99m complex with the YKC portion is only a possibility or probability. We decline to interpret Dr. Lister-James' testimony that a mixture will form as meaning that the formation of the MADAT complex is not an invariable result of radiolabeling Rodwell's compound with Tc-99m.

Dr. Lister-James' did not testify that Tc-99m does not complex at the YKC portion of Rodwell's compound. Rather, Dr. Lister-James testified that not all of the 100 microgram Rodwell sample formed the complex. Specifically, Dr. Lister-James stated that "if more than one thiol-containing amino acid sequence is present in the molecule a mixture of products and low yields are observed." (MX 1025, ¶ 16). Even accepting Dr. Lister-James' testimony at face value, we find that the preponderance of the evidence establishes that a sample of Rodwell's YKC will inevitably form a measurable amount of the Tc-99m complex at the YKC portion of the Rodwell compound. More precisely, consistent with Dr. Lister-James' declaration that reports up to 65% RCP values for the Rodwell compound, we credit Dr. Linder's testimony and

supporting HPLC and NMR evidence that Tc-99m will coordinate in a measurable amount to the YKC sequence of Rodwell's YKC metal binding peptide and that this is the predominant coordination. (PX 2046, ¶¶ 35, 95).

c. Teachings of Cox WO/92/21383

McBride argues that the Rule 641 rejection is based upon Dr. Linder's testimony that technetium will bind the Rodwell compound to form a 5:5:5 configuration with technetium coordinating the YKC portion of the compound. (Paper No. 101, ¶ 11). McBride directs our attention to the Cox reference teaching that:

> In connection with the excellent properties of the labeled product and the ready availability of somatostatin as a starting peptide, a labeled polypeptide is preferred of the general formula R_1-Ala-Gly-Cys-Lys-Asn-Phe-Phe-(D)Trp-Lys-Thr-Phe-Thr-Ser-Cys-R_2 the metal radionuclide being selected from the group consisting of Tc-99m, Re-186 and Re-188 which as a cation is bound covalently to the mercapto groups of the cysteine amino acid radicals.

(PX 2006, p. 6, lines 14-25).

We have reviewed the cited portion of the Cox reference but find that it is not inconsistent with our finding that Tc-99m will invariably bind to the YKC portion of Rodwell's compound. Specifically, both Dr. Lister-James and Dr. Linder determined that Tc-99m will form a mixture of chelate complexes. That a portion of a Rodwell compound sample, like the aforementioned Cox compound, may form a chelate complex with both cysteine amino acid radicals does detract from our determination that a sample of Rodwell's YKC will inevitably form a measurable amount of the Tc-99m complex at the YKC portion of the Rodwell compound.

Based upon the evidence of record, we find that each and every limitation presented in McBride claims 2, 3 and 7 is either explicitly taught by the Rodwell references or are a natural consequence thereof. Further, McBride claim 10 was rejected as obvious over the Rodwell references in light of testimony made by McBride's declaration of Mr. Richard Dean. (Paper No. 97, p. 24). McBride's response to the Rule 641 rejection failed to explain why the differences between the Rodwell references and McBride claim 10 were unobvious to one skilled in the art. Accordingly, we maintain the Rule 641 rejection of McBride claim 10 and hold it unpatentable.

B. Order to Show Cause for Pollak's Corresponding Claims

As discussed in the Rule 641 Rejection and Order to Show Cause (Paper No. 97), Pollak alleged that McBride's corresponding claims 2, 3, 7 and 10 were unpatentable over the Rodwell references. Yet, in making these allegations Pollak has consistently failed to explain why Pollak's involved corresponding claims are patentable over the Rodwell references.

Pollak has had ample opportunity to distinguish its claimed invention from the peptides taught by the Rodwell references. For example, Pollak Preliminary Motions 1 and 6 rely upon the teachings of the Rodwell references for the unpatentability of McBride's claims, but fail to explain why Pollak's corresponding claims are not likewise unpatentable. Rather than explain the distinguishing features of its claims at the Oral Hearing of March 26, 2003, Pollak requested that the Board issue an Order to Show Cause. Pollak responded to the Order to Show Cause by arguing that if the Board finds McBride's claims patentable, then Pollak's claims are patentable for the same reasons as McBride. (Paper No. 104). As discussed above, we hold McBride

claims 2, 3, 7 and 10 unpatentable over the teachings of the Rodwell references.

Pollak is under an Order to Show Cause why its presently corresponding claims are patentable over the Rodwell references. (Paper No. 97). Pollak has failed to show cause why its presently corresponding claims are patentable over these references. Accordingly, we hold that Pollak's corresponding claims:

Pollak 5,662,885:	1-9 and 14-15
Pollak 5,780,006:	1-3, 5-6, 8-11 and 15-18
Pollak 5,976,495:	1-3, 5-6, 8-11 and 14-25

are unpatentable over the teachings of the Rodwell references.

C. McBride Preliminary Motion 3

When an Administrative Patent Judge makes a Rule 641 rejection, a party may "present its views, including any argument and any supporting evidence, and, in the case of the party whose claim may be unpatentable, any appropriate preliminary motions under §§1.633(c), (d) and (h)." 37 C.F.R. §1.641(a). Pursuant to Rule 633(c), McBride Preliminary Motion 3 requests that McBride claims 2, 3, 7 and 10 be amended. (Paper No. 102). Pollak opposes this request. (Paper No. 112).

McBride's request to amend its claims fails to properly respond to the Rule 641 rejection. McBride Preliminary Motion 3 fails to identify how the proposed amendment would distinguish its claims from the teachings of the Rodwell references. For example, McBride Preliminary Motion 3 states:

> 7. It is proposed to amend claims 2, 3, 7 and 10 - all of the McBride claims that correspond to the count - so as to avoid any ambiguity regarding the three

> functional limitations in the McBride claims. These functional limitations are readily discernable from the McBride application, as indicated in paragraphs 1 and 2 above.

McBride fails to explain how the correction of the potential "ambiguities" in the claims distinguishes Rodwell's YKC metal binding peptide from the claimed invention.

McBride's reply argues that:

> The rationale behind Pollak's assertion that "McBride's amendment totally ignores the Rule 641 Rejection" is not understood. In "fact" paragraphs 12, 33, 48 and 57, there are statements to the effect that the proposed amended claims are patentable over the YKC fibrinogen compound of the Rodwell references. ***This is technically true but McBride Motion 3 is part of the McBride Response to the Rule 641 Rejection which was concurrently served and filed.***

(Paper No. 117, p. 6, emphasis added). The Standing Order (Paper No. 2) governs procedures in this interference and explicitly provides that "[a]rguments presented in one paper shall not be incorporated by reference to another paper." (Paper No. 2, ¶ 13). The prohibition against incorporation is intended to minimize the possibility that arguments will be missed or overlooked. We have reviewed the McBride Response to Rule 641 Rejection (Paper No. 101), McBride Preliminary Motion 3 (Paper No. 102) and McBride Reply 3 (Paper No. 117) but were unable to determine where McBride specifically identified how the proposed amendment was necessary to overcome the Rule 641 rejection.

Additionally, even if McBride had directed our attention to proposed additional distinguishing limitations for its claims, McBride's proposed amendment fails to comply with the interference rules. Rule 637 requires that a moving party show the patentability to the applicant for each claim proposed to be amended. 37 C.F.R. §1.637(c)(2)(iii). To show patentability means that a party must establish that a claim proposed to be designated as corresponding to a

proposed count complies with the written description requirement of the first paragraph of 35 U.S.C. § 112. Notice of the Chief Administrative Patent Judge of Nov. 6, 1998, "Interference Practice -- Interference Rules Which Require a Party to 'Show the Patentability' of a Claim," 1217 Off. Gaz. Pat. & Tm. Office 17 (Dec. 1, 1998). In requesting entry of its amendment, McBride failed to identify how the proposed claims comply with the written description requirement.

We note that McBride's reply argued that:

> Much of the above discussion with regard to Rule 637(c)(2) is applicable to the assertion that McBride's amended claims fail to satisfy 35 U.S.C. §112. As previously pointed out, party McBride is not seeking to redefine the invention; rather, the amendments have been proposed in order to narrow the scope of the claims so as to avoid any possible ambiguous meaning.

(Paper No. 117, p. 9). A narrowing amendment is an amendment that defines the invention and must comply with the rules that require a party to show the patentability of its proposed amendment.

McBride has failed to demonstrate that its amendment was necessary to respond to the Rule 641 rejection and has failed to comply with the requirement that a motion seeking to amend the claims show the patentability to the applicant for the amended claims. McBride Preliminary Motion 3 is ***denied***.

D. McBride Preliminary Motion 4

McBride Preliminary Motion 4 requests that the following Pollak claims be designated as corresponding to the count:

U.S. Patent No. 5,662,885, claims 10 and 11;
U.S. Patent No. 5,780,006 claims 12 and 13; and
U.S. Patent No. 5,976,495 claims 12, 13, 26 and 27.

(Paper No. 103, p. 1). McBride alleges that these claims involve the peptide sequences -TKPPR or -GTKPPR and that these peptides are obvious over Count 1 in light of the prior art. (Paper No. 103, ¶¶ 4 and 6). Pollak opposes. (Paper No. 113).

According to McBride:

> The issue with respect to the Pollak claims that McBride now seeks to have designated to correspond to the Count has, essentially, been previously argued. It is believed that the action of the Board in designating these claims as not corresponding may be due to an oversight since the issue as to these particular claims was not addressed in the Memorandum, Opinion and Order.

(Paper No. 103, ¶ 12). McBride originally sought to have these particular Pollak claims designated as corresponding to McBride's proposed count. (McBride Preliminary Motion 1, Paper No. 31). This motion was denied in the Memorandum, Opinion and Order. (Paper No. 95). As McBride's motion to substitute its proposed count was denied, McBride's proposed claim correspondence for its proposed count was moot.

The parties were aware that the count used to declare the interference contained a clear and obvious error. As discussed in Paper No. 52, there were three possible counts in this interference:

> A reoccurring theme of this interference is the question of what is the proper count. The APJ noted that there are three potential counts for this interference: (i) ***there is the present count with the -COOZ1 replaced by -COZ1***; (ii) McBride proposed Count 2; and (iii) Pollak proposed Count 2.

(Paper No. 52, page 3, emphasis added). The parties were on specific notice that the interference would be redeclared with the -COZ1 option should the parties' proposed counts be denied. As

the parties' proposed counts were denied, the interference was redeclared in Paper No. 96 with the -COZ1 count.

McBride's request to designate additional Pollak claims as corresponding to the count is belated. McBride was fully entitled to request that Pollak's -TKPPR or -GTKPPR be designated as corresponding to the -COZ1 count in interference. McBride chose not to file such a motion.

Under Rule 641 a party whose claim may be unpatentable may file an appropriate motion under Rule 633(c), (d) and (h). Rule 641 permits the filing of such motions to allow a party to respond to the rejection of their claims. For example, a party may file a Rule 633(c) motion to amend its claims in an effort to obviate the basis for the rejection, a Rule 633(d) motion to substitute a different application for the one in interference or a Rule 633(h) motion to add a reissue to the interference.

McBride's preliminary motion seeking to designate Pollak's claims as corresponding to the count does not properly respond to the Rule 641 rejection. The question of Pollak's claim correspondence is a separate and distinct issue from the question of whether or not McBride's claims are patentable over the Rodwell references cited in the Rule 641 rejection. As McBride Preliminary Motion 4 does not further aid the panel in understanding the patentability of McBride's claims, McBride Preliminary Motion 4 is not an "appropriate" responsive motion under Rule 641.

McBride appears to insinuate that the Order to Show Cause against Pollak should be extended to Pollak's -TKPPR or -GTKPPR claims. (Paper No. 103, ¶ 12). Our decision in this interference is intended to resolve issues that have been timely raised and fully developed. As

McBride has ever explicitly raised the issue of the patentability of Pollak's -TKPPR or -GTKPPR claims over the Rodwell references, we will not extend the Order to Show Cause to these particular claims.[3]

McBride Preliminary Motion 4 is not an appropriate Rule 641 responsive motion as it does not seek to address the Rule 641 rejection. Further, McBride did not seek to raise the issue of Pollak's claim correspondence for the –COZ1 count during the regularly scheduled preliminary motions phase of this interference. Finally, McBride has not shown good cause for the belated filing of its motion. *See*, 37 C.F.R. §1.645(b). McBride Preliminary Motion 4 is ***denied***.

McBride has argued that Pollak Oppositions 3 and 4 (Paper Nos. 112 and 113) were not timely filed and should not be considered. (See, e.g., Paper No. 117, p. 10). In arguing that Pollak's oppositions were not timely filed, McBride has failed to demonstrate how the alleged untimeliness prejudiced McBride. Also, in reviewing the Orders that set times for opposing McBride Preliminary Motions 3 and 4, we find that Pollak's interpretation of the dates for filing is not unreasonable. As there was no actual prejudice to the potentially late filing of the oppositions to McBride Preliminary Motions 3 and 4 and as there may have been some ambiguity as to the dates set, we conclude that Pollak's filing was not belated and specifically authorize the entry of Pollak's oppositions to ensure a complete record for purposes of appeal.

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[3]Should McBride believe that Pollak's patented -TKPPR or -GTKPPR claims are unpatentable over prior art, McBride is entitled to file a request for reexamination.

E. Pollak's Deferred Preliminary Motions

Pollak has filed six prior art patentability motions against McBride's corresponding claim, which are claims 2, 3, 7 and 10. (Pollak Preliminary Motions 1, 2, 3, 6, 7 and 8). The Memorandum, Opinion and Order (Paper No. 95) deferred resolution on these motions awaiting a decision on the Rule 641 rejection of McBride's claims. We have now determined that McBride claims 2, 3, 7 and 10 are unpatentable over the Rodwell references. In light of this determination, we dismiss Pollak's deferred preliminary motions as ***moot***.

F. Conclusion

Since neither party has patentable claims to form the basis for the formulation of an appropriate count for contesting priority, it is not appropriate or possible to proceed to the priority phase of this interference. A judgment is being issued contemporaneously with this decision holding that the parties are not entitled to the subject matter of their respective involved claims.

It is:

ORDERED that Pollak Preliminary Motion 1 is ***dismissed as moot.***

FURTHER ORDERED that Pollak Preliminary Motion 2 is ***dismissed as moot.***

FURTHER ORDERED that Pollak Preliminary Motion 3 is ***dismissed as moot.***

FURTHER ORDERED that Pollak Preliminary Motion 6 is ***dismissed as moot.***

FURTHER ORDERED that Pollak Preliminary Motion 7 is ***dismissed as moot.***

FURTHER ORDERED that Pollak Preliminary Motion 8 is ***dismissed as moot.***

FURTHER ORDERED that McBride Preliminary Motion 3 is ***denied.***

FURTHER ORDERED that McBride Preliminary Motion 4 is ***denied.***

FURTHER ORDERED that a copy of this decision be placed in the involved McBride U.S. Application No. 08/253,973 and Pollak's involved U.S. Patents 5,662,885, 5,780,006 and 5,976,495.

SALLY GARDNER LANE)
Administrative Patent Judge)
)
)
MICHAEL P. TIERNEY) BOARD OF PATENT
Administrative Patent Judge) APPEALS
) AND
) INTERFERENCES
)
)
MARK NAGUMO)
Administrative Patent Judge)

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INTERFERENCE DIGEST

Interference No. 104,789 Paper No. 49

Name: William McBride, et al.

Serial No.: 08/253,973 Patent No.

Title: Monoamine, diamide, thiol-containing metal chelating agents

Filed: 06/03/94

Interference with Alfred Pollak et al.

DECISION ON MOTIONS

Administrative Patent Judge,_____ Dated,_____

FINAL DECISION

Board of Patent Appeals and Interferences, Abeyance Dated, 4-8-04

Court,_____ Dated,_____

REMARKS

This should be placed in each application or patent involved in interference in addition to the interference letters.